REMARKS

Claims 2, 5-8, 10, 14-17, 29-36 and 38-42 are pending. Claims 5, 7-8, 14, 16-17, and 34-36 stand withdrawn from further consideration by the Examiner because they are drawn to non-elected species of elected Group II. Claims 1, 3-4, 11-13, 18-28 and 27 were cancelled in previous responses to office communications. In addition, Applicant has cancelled withdrawn claims 38-40 because they disclose the same subject matter as withdrawn claims 33-36. All of the claims, pending, withdrawn, or cancelled are reiterated herein as required by the "Revised Amendment Practice", effective date July 30, 2003.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 2, 6, 10, 15, 29-32 and 38-42 are rejected under 35. U.S.C. § 112, second paragraph for being indefinite. Claims 2, 6, 10, 15, 29-32 and 38-42 have been amended to clarify that the term "T cell activator" includes T cell activators other than IL-2. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Double Patenting Rejections

Claims 2, 6, 10, 15 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-4 of U.S. Patent No. 6, 447, 765 in view of U.S. Patent No. 6,406,696.

Without admitting the propriety of the rejection and in the interest of furthering prosecution, a terminal disclaimer listing U.S. Patent No. 6, 477,765 is submitted herewith. Accordingly, Applicant respectfully requests withdrawal of the double patenting rejection based on U.S. Patent No. 6,477,765.

U.S. Patent No. 6, 406, 696 discloses a method for stimulating an immune response comprising activating T cells with anti-CD3. However, there is no teaching or disclosure in U.S. Patent No. 6, 406, 696 regarding the use of a suppressive composition comprising TGF-β, IL-2, and a T cell activator to suppress an immune response, such as suppression of the immune response associated with graft versus host disease (GVHD).

In contrast, the claims of the present invention disclose a method for suppressing an immune response in a recipient patient against donor cells, thereby preventing GVHD. The method comprises treating donor PBMC with a suppressive composition comprising TGF-β, IL-2, and at least one other T cell activator for a time sufficient to induce T cell tolerance in said PBMC. Once T cell tolerance has been induced, the treated cells can then be introduced into a recipient without elicting GVHD.

To establish a prima facie case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) M.P.E.P. §2143.

Applicant submits that U.S. Patent No. 6, 406, 696 does not teach or suggest every limitation of the pending claims as U.S. Patent No. 6, 406, 696 does not teach or disclose methods for suppressing an immune response comprising treating PBMC from a donor with a suppressive composition comprising TGF-β, IL-2 and a T cell activator to ameliorate the immune response associated with GVHD in a recipient patient. Accordingly, Applicant respectfully requests withdrawal of the rejection based on U.S. Patent No. 6, 406,696.

Claims 29-33 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-4 of U.S. Patent No. 6, 447, 765 in view of Sykes et al., 1990, Cell Immunol., 129: 478-93.

Without admitting the propriety of the rejection and in the interest of furthering prosecution, a terminal disclaimer listing U.S. Patent No. 6, 477,765 is submitted herewith. Accordingly, Applicant respectfully requests withdrawal of the double patenting rejection based on U.S. Patent No. 6,477,765.

Sykes et al teach methods for isolating and enriching natural suppressor (NS) cells. The methods comprise isolating NS cells from T cell-depleted bone marrow and enriching the population of isolated NS cells by culturing the cells in the presence of IL-2 or other cytokines. Although Sykes teaches the use of other cytokines, there is no teaching in Sykes regarding the use of TGF-β for this purpose.

In contrast, the present claims teach methods for inducing T-cell tolerance in a CD3+CD4-CD8- subset from donor PBMC and then treating that subset with a suppressive composition comprising TGF-β, IL-2 and at least one other T cell activator.

Applicant submits that Skyes et al. does not teach or suggest every limitation of the pending claims as there is no teaching or disclosure in Skyes et al. of a method for inducing T cell tolerance in CD3+CD4-CD8- cells using a suppressive composition comprising TGF-β, IL-2 and at least one other T cell activator. Applicants respectfully request withdrawal of the rejection based on Skyes et al.

Please direct further questions in connection with this Application to the undersigned at (415) 781-1989.

Respectfully submitted,
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